U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control

Meeting of the Breast and Cervical Cancer Early Detection and Control Advisory Committee
November 6-7, 2014
Atlanta, Georgia

Record of the Proceedings

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EARLY DETECTION AND CONTROL ADVISORY COMMITTEE
ATLANTA, GEORGIA
November 6-7, 2014

Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control (DCPC), convened a meeting of the Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC). The proceedings were held on November 6-7, 2014 in the Columbia Building, Room 1064/1065, CDC University Office Park in Atlanta, Georgia.

Information for the public to attend the BCCEDCAC meeting in person or participate remotely via webinar or teleconference was published in the *Federal Register* in accordance with Federal Advisory Committee Act regulations. All sessions of the BCCEDCAC meeting were open to the public (*Attachment 3: Participants' Directory*).

BCCEDCAC is chartered to provide advice and guidance to the HHS Secretary and the CDC Director regarding the early detection and control of breast and cervical cancer. BCCEDCAC's recommendations focus on national program goals and objectives, implementation strategies, and program priorities (including surveillance, epidemiologic investigations, policy, education and training, information dissemination, and professional interactions and collaborations).

Opening Session: November 6, 2014

Jameka R. Blackmon, MBA, CMP
Public Health Advisor, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
BCCEDCAC Designated Federal Officer

Ms. Blackmon conducted a roll call and announced that the 19 voting members and *ex-officio* members in attendance constituted a quorum for BCCEDCAC to conduct its business on November 6, 2014 (*Attachment 2: Roster of the BCCEDCAC Membership*). She called the proceedings to order at 9:04 a.m. and welcomed the participants to day 1 of the meeting. None of the voting members publicly disclosed conflicts of interest for any of the published agenda items (*Attachment 1: Published Meeting Agenda*).

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Chair

Dr. Mullen also extended her welcome and announced that biographical sketches of five new members were included in the meeting packets. She asked the participants to join her in welcoming the new members to their first BCCEDCAC meeting.

New BCCEDAC Member	Affiliation
Wendy Rosamund Brewster, PhD, MPH	Associate Professor, Department of Obstetrics and Gynecology, University of North Carolina School of Medicine
Lisa C. Flowers, MD	Associate Professor, Department of Obstetrics and Gynecology, Emory University School of Medicine
Carolyn Muller, MD	Director, Division of Gynecologic Oncology University of New Mexico Cancer Center
Marcus Plescia, MD, MPH	Director, Mecklenburg County (NC) Health Department
Richard C. Wender, MD	Chief Cancer Control Officer American Cancer Society

Dr. Mullen thanked CDC for its tireless efforts in providing both domestic and international public health officials with outstanding expertise, technical assistance and support during the ongoing Ebola outbreak.

Dr. Mullen emphasized that because the Affordable Care Act (ACA) has been fully implemented over the past year, BCCEDCAC would devote considerable time during the meeting to provide CDC with formal advice and recommendations on the future of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) in a health reform environment. She concluded her opening remarks by reviewing the meeting agenda.

Overview of Federal Advisory Committee Roles and Responsibilities

Terry Wheeler
Conflict of Interest Specialist
Management Analysis and Services Office
Centers for Disease Control and Prevention

Mr. Wheeler presented an overview of the roles and responsibilities of Federal Advisory Committees (FACs). Congress created the Federal Advisory Committee Act (FACA) as the legal foundation for establishing, overseeing and managing FACs. Congress determined that FACs are a useful and beneficial mechanism for the federal government to obtain expert advice, ideas and diverse opinions.

Rigorous FACA regulations ensure that several key provisions are met. A new FAC is established only if its purpose is determined to be essential. Each FAC is designed to provide advice that is relevant, objective and open to the public. Standards and uniform procedures govern the establishment, operation, administration and duration of all FACs. Congress and the public must have knowledge of the purpose, membership, activities and cost of each FAC. A FAC is terminated when its intended purpose has been fulfilled.

FACA specifically defines and serves as a formal process for the establishment, oversight, operation and management of all FACs. Congress regularly reviews the activities of each FAC to determine if its abolishment or merger with another FAC is warranted, if the FAC's responsibilities should be revised, or if the FAC's necessary functions are performed by another FAC. The U.S. President has delegated all functions of FACA to the General Services Administration (GSA) (e.g., submitting an annual report for the President's consideration, monitoring and reporting FACA compliance, and providing written guidance and FACA training).

Agency leadership establishes uniform administrative procedures and management controls for FACs that are consistent with GSA directives. Committee Management Specialists and Committee Management Officers consult with agency leadership to oversee and supervise the establishment, public accessibility and ongoing accomplishments of FACs. "Mandated" FACs are established by statute or the President through an Executive Order. "Discretionary" FACs are established when an agency determines the need for advice and recommendations in consultation with GSA and issues a public notice.

All FACs must be established with three components: a written charter to outline and memorialize the purpose of the FAC, a Designated Federal Officer (DFO) to oversee the operation of the FAC, and appointed members with a designated chair. The primary role of FACs is to provide federal officials and the nation with access to expert advice on a broad range of issues that affect federal policies and programs. FACs also ensure that the public is given opportunities to actively participate in the federal government decision-making process.

FACs can include members in three distinct categories to ensure that points of views are fairly balanced and the intended functions are well represented. "Special Government Employees" (SGEs) are private citizens who are appointed based on their specific area of expertise. SGEs are subject to the Standards of Ethical Conduct for Employees of the Executive Branch. "*Ex-Officio* Members" are federal officials who represent their respective agencies as subject-matter experts. "Liaison Representatives" serve as the voice for special interest groups, organizations or affected populations.

FACs are required to comply with FACA regulations to convene meetings. A notice announcing the meeting, including its purpose, agenda, date/time, location and contact information, must be published in the *Federal Register* in advance. The DFO must approve the agenda and attend the entire meeting. The meeting must allow the public an opportunity to submit oral or written comments. Detailed minutes of each meeting must be developed and made available to the public. All other official records must be generated and maintained for the duration of the FAC

in accordance with the Federal Records Act and National Archives and Records Administration regulations.

FACs are allowed to use alternate mechanisms to conduct activities outside of their full memberships. A "subcommittee" must be formed with at least one member of the parent FAC and is required to report directly and submit work products to the parent FAC. CDC policy requires all of its subcommittees to comply with FACA regulations. A "workgroup" must be formed with at least two members of the parent FAC or subcommittee and is required to report directly to either of these two bodies. Because workgroups are not subject to FACA regulations, their members cannot give advice or propose recommendations directly to the agency. Workgroups are formed for a designated period of time to complete specific projects or tasks, such as conducting research or gathering and analyzing data.

FACs have a rich history in providing significant recommendations to the President, federal government agencies and the nation on a variety of issues. For example, the Commission on Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction offered critical guidance following the 9/11 terrorist attacks. The CDC Advisory Board on Radiation and Worker Health continues to provide valuable input on the quality of dose reconstruction efforts, development and scientific validity of guidelines, and potential radiation exposure to U.S. Department of Energy workers.

Formal advice and recommendations of FACs are submitted by and communicated at several levels, including FAC management staff, agency and department leadership, the GSA Committee Management Secretariat, U.S. President and Congress.

In addition to regulations regarding the establishment, oversight and management of FACs, FACA also outlines laws for the ethics and financial disclosures of SGEs. Congress created the SGE category to apply an important, but limited set of conflict of interest (COI) requirements to persons who provide temporary service to the federal government. "Temporary service" is not to exceed 130 days during any period of 365 consecutive days with or without compensation. SGEs (e.g., FAC members, individual experts or consultants) provide external expertise or perspectives that might be unavailable in an agency's regular workforce.

SGEs must uphold the highest ethical standards to assure public trust during their public service. SGEs appointed as FAC members are required to file a confidential Financial Disclosure Report (FDR), but this document is not made available to the public. SGEs must include the following information in their FDRs: assets, income, liabilities, agreements/ arrangements, external non-federal positions, curriculum vitae/resume, Foreign Activities Questionnaire, and Research Support/Project Funding Report. The SGE's FDR is approved after the agency verifies its completeness, accuracy and potential COIs.

The agency rigorously reviews ethics rules and laws to ensure that SGEs avoid COIs. For example, one statute prohibits SGEs from participating or acting in any particular government matter with a direct or predictable effect on the financial interests of themselves or persons in certain relationships (e.g., spouses, minor children and general business partners). A variety of issues can cause COIs for SGEs, including stocks, bonds, consulting arrangements, grants, contracts, employment, or interests through a business ownership, partnership or limited liability corporation.

For purposes of determining a COI, the government broadly defines a "particular matter" as the deliberations, decisions or actions that are focused on the interests of specific persons or entities or an identifiable and discrete class of persons or entities (e.g., industry, group of manufacturers or healthcare providers). A particular matter does not extend to broad policy options or considerations directed toward the interest of a large and diverse group of individuals, but specific parties might be involved through a contract, grant or case in litigation.

SGEs who serve on FACs are covered by certain exceptions to the COI statute, but these exceptions have several important limitations. The matter cannot have a special or distinct effect on SGEs or their non-federal employers other than as part of a class. The exception does not cover interests arising from the ownership of stock or other financial interests in the employer or prospective employer. Non-federal employment must involve an actual employee/ employer relationship rather than an independent contractor or consultant position.

A particular matter will have a "direct" effect on a financial interest if a close causal link exists. However, a particular matter that has an effect on a financial interest only as a consequence of its impact on the general economy is not considered to have a direct effect on a financial interest. A particular matter will have a "predictable" effect if a real possibility exists that the matter will affect a financial interest. Circumstances related to an SGE's relationships outside of the government might lead to questions of whether an appearance of a lack of impartiality exists. The agency's ethics officials should decide whether the SGE is allowed to participate in a particular matter.

SGEs with an interest in representing organizations to the government during their public employment must comply with two COI statutes that impose restrictions on outside activities, particularly those involving the representation of others before the government. SGEs are prohibited from receiving compensation for representational services in any particular matter in which the United States is a party or has a direct and substantial interest. However, SGEs may represent others or receive compensation for representational services in connection with particular matters of general applicability that do not involve specific parties. Restrictions on SGEs are narrowly defined to focus only on those particular matters in which the SGE substantially and personally participated at any time.

The Standards of Ethical Conduct for Employees of the Executive Branch outline a number of provisions to ensure that SGEs do not misuse their positions. Because public service is a public trust, each SGE has a responsibility to the U.S. government and its citizens to place loyalty to the Constitution, laws and ethical principles above private gain. Any non-public information SGEs receive because of their federal employment that has not been made available to the general public cannot be used for financial gain or private interest. SGEs have a duty to protect, conserve and use government property in an authorized manner only.

SGEs might be prohibited from receiving outside compensation for teaching, speaking or writing if the activity relates to their official government duties. Persons who hold offices of profit or trust in the U.S. government are prohibited from having any position in or receiving any payment from a foreign government. SGEs are prohibited from accepting gifts from a "prohibited source" or as a result of their official position. SGEs also are subject to the criminal bribery and illegal gratuity statute, prohibitions on personal fundraising for nonprofit organizations, and restrictions on certain political activities.
An SGE who has participated as a government employee in a particular proceeding is prohibited from providing expert testimony in that matter. A more restrictive standard applies to

a smaller class of SGEs who are appointed by the President, serve on a commission established by statute, or have served or are expected to serve more than 60 days in a period of 365 consecutive days. The standard applies to any proceeding in which the SGE's agency is a party or has a direct and substantial interest. SGEs should contact the agency's ethics officials of the DFO to obtain additional assistance and information.

Update by the CDC Division of Cancer Prevention and Control

Pamela Protzel Berman, PhD, MPH
Acting Director, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Dr. Berman described DCPC's ongoing and future activities in her portion of the update. DCPC held a Program Director's meeting with its grantees in August 2014. DCPC is continuing to support the global Ebola response by deploying staff to Africa, U.S. quarantine stations and the CDC Emergency Operations Center; developing communications materials; and providing logistical assistance. Dr. Berman was pleased to announce that Dr. Lisa Richardson would begin serving as the new DCPC Director on November 17, 2014.

DCPC recently released a new *Vitalsigns* Report that emphasized the ability to prevent cervical cancer and highlighted missed opportunities for screening. The report noted that of 8 million women who were not screened in the past five years in 2012, 7 out of 10 women had a regular physician and health insurance.

Efforts are underway to improve cervical cancer screening and human papillomavirus vaccination (HPV) rates. CDC recently awarded new grants to improve HPV vaccination rates, support cancer prevention, strengthen partnerships with Cancer Control Coalitions (CCCs), and enhance healthcare delivery. The National Cancer Institute (NCI) will award supplemental funding of up to $2.7 million to 18 Cancer Centers to improve HPV vaccination uptake through partnerships with state and local immunization programs and CCCs.

DCPC displayed materials at the 6th Annual Congressional Women's Softball Game and conducted other activities to raise awareness of breast cancer in young women. Most notably, DCPC released the Know:BRCA online tool to assist young women and providers in assessing and better understanding the risk for hereditary breast and ovarian cancer. DCPC plans to launch a full-scale social media campaign in the spring of 2015 to educate young women and providers on breast health, breast cancer risk factors and survivorship. DCPC launched its new Facebook page that is dedicated to breast cancer.

CDC recently awarded a new cycle of grants to 26 Prevention Research Centers (PRCs) to conduct research projects that promote health and prevent disease in underserved communities across the nation. CDC and NCI recently co-funded the Cancer Prevention and Control Research Network that includes eight centers representing academic institutions, public health and community partners to reduce the burden of cancer, particularly among disproportionately affected populations. CDC awarded new grants to health departments and community-based organizations (CBOs) to address the leading risk factors for chronic diseases and cancer, including tobacco use, poor nutrition and physical inactivity.

Faye Wong, MPH
Chief, Program Services Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Ms. Wong presented an NBCCEDP status report in her portion of the update. NBCCEDP was established by law in 1990 and serves as the only national screening program in the United States. CDC funds 67 Breast and Cervical Cancer (BCC) Programs in all 50 states and the District of Columbia, 11 tribes and tribal organizations, and 5 U.S. territories. Enactment of ACA in 2010 marked the beginning of changes and opportunities for NBCCEDP, particularly since BCC screening would be available to millions more women.

NBCCEDP has served 4.6 million women since 1991, conducted 11.6 million screenings, and diagnosed 64,718 breast cancers, 3,576 cervical cancers, and 167,169 pre-malignant cervical lesions. NBCCEDP serves ≈500,000 women annually. Total funding awarded to grantees decreased from ≈$157 million in program year (PY) 1 to ≈$154 million in PY3 over the fiscal year (FY) 2012-FY2014 funding cycle. Funding awarded to individual grantees ranged from $238,323 for small U.S. territories to ≈$8.7 million for large, densely populated states.

Based on 2010-2012 data, NBCCEDP reaches 9.8% of eligible women for breast cancer screening and 11.1% of eligible women for cervical cancer screening. Of all eligible women reached, NBCCEDP screens 10.6% for breast cancer and 6.5% for cervical cancer. Although ACA now covers low-income and uninsured women, a significant proportion will continue to be eligible for NBCCEDP services.

DCPC staff and several external authors published the "National Breast and Cervical Cancer Early Detection Program: Two Decades of Service to Underserved Women" monograph in *Cancer* in August 2014. The monograph particularly emphasized ACA as an important opportunity for public health and cancer screening due to increased access for a large, new population of women.

The first ACA open enrollment period was from October 1, 2013 to March 31, 2014 and resulted in ≈8 million enrollees. DCPC has taken several actions since that time to prepare for the second ACA open enrollment period beginning on November 15, 2014 to February 15, 2015. A survey was administered to grantees to assess program implementation, track related changes over the five-year cooperative agreement, and evaluate training and technical assistance (TA) needs of grantees related to health reform.

Of 67 BCC Programs, training and TA were requested by ≈46% grantees for health reform and covered preventive services and by ≈38% of grantees for Health Insurance Exchanges (HIEs). Grantees reported that limited knowledge of NBCCEDP-eligible populations and lack of support and direction for ACA implementation were the two most challenging issues. DCPC intends to host annual webinars to disseminate survey findings, release individual grantee reports, and include more ACA-related items in the future.

In addition to administering the survey, DCPC also provided extensive TA and support to grantees, designated staff with expertise in ACA, and drafted an ACA messaging tool for grantees to adapt for their specific patient populations, provider networks and partners. The messages include templates to facilitate ACA enrollment, target outreach to hard-to-reach populations, and enhance community-clinical linkages.

DCPC releases monthly *ACA Reference Guides* that are designed to share credible resources, increase knowledge, assess needs, obtain feedback and increase communication. Each guide is devoted to a specific topic, such as enrollment in and coverage of preventive services in expanded Medicaid in the May 2014 edition and information on the distribution of non-elderly uninsured persons by Federal Poverty Level (FPL) in the July 2014 edition. The guides also help to increase grantee knowledge and understanding of HIEs and mandates in their individual states.

DCPC is making efforts at this time to redesign NBCCEDP with a greater population-based approach to cancer screening. New changes at the health system level will require NBCCEDP to shift from opportunistic care to organized care of its eligible population. Evidence-based interventions (EBIs) (e.g., patient and provider reminder systems, provider assessment feedback and structural changes) will need to be implemented to achieve this goal. In both Medicaid and non-Medicaid expansion states, creative and innovative strategies, non-traditional models, and new opportunities and partnerships will be important for the future success of NBCCEDP.

Overall, NBCCEDP is a successful organized screening program. ACA offers important new opportunities for public health and cancer screening, but change and opportunities are not simple or automatic. The ability to anticipate and lead change will serve as the foundation for the future of NBCCEDP.

BCCEDCAC expressed a great deal of support for CDC's plans to redesign NBCCEDP as a population-based cancer screening program. However, several members noted that this goal could not be achieved unless the longstanding problem of estimating the denominator of the NBCCEDP population reached is resolved. The BCCEDCAC members proposed strategies to overcome barriers to obtaining individual-level data and shifting to a population-based screening approach.

- CDC and its federal partners should award funds to train BCC Programs in conducting neighborhood sampling and geocoding at the local level. Data from priority geographic locations could build community capacity in targeting local populations in most need and also could serve as a representative sample to improve national BCC screening rates. National quality measures for monitoring and evaluating NBCCEDP over time in a health reform environment should be developed as well.
- CDC should partner with managed care organizations and large health plans to assure the quality of BCC screening and services in clinical settings. These health systems have obtained better estimates than public health of denominators of their patient populations.
- CDC and the Health Resources and Services Administration (HRSA) should collaborate on increasing routine BCC screening in communities by building a better health system infrastructure in Federally Qualified Health Centers (FQHCs).
- CDC should offer incentives to community health systems to build stronger relationships with public health and implement population-based screening approaches.
- CDC should clearly define the role of NBCCEDP in ACA by identifying overlap and gaps between these two areas. For example, CDC's ability to fund direct services in non-Medicaid expansion states is questionable, particularly to meet the needs of uninsured persons in the coverage gap.
- CDC should explore the possibility of advising BCC Programs to place more emphasis on women at <100% FPL in non-Medicaid expansion states.

PANEL PRESENTATION: IMPACT OF ACA ON THE NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM

Jacqueline Miller, MD, Capt. USPHS
Medical Officer, Program Services Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Dr. Miller introduced a panel of speakers to describe the experiences and perspectives of select states regarding the impact of ACA on NBCCEDP. The overviews are summarized below.

Nebraska Experience

Melissa Leypoldt, RN
Program Director, Women's & Men's Health Programs
Nebraska Department Health and Human Services

Ms. Leypoldt described the impact of ACA on the Nebraska BCC Program. Nebraska has been responding to significant changes in public health over the past few years, including the new health reform environment with ACA and medical home models, changes in the political climate, less funding for more activities, a shift to population-based screening, the need to create a culture of wellness with emphasis on prevention, and utilization of EBIs, particularly system changes within clinical practices and population-level patient navigation.

Nebraska took advantage of several opportunities to prepare for health reform. CDC included new language in the most recent Funding Opportunity Announcements (FOAs) for NBCCEDP and the Colorectal Cancer Control Program. The NBCCEDP Director's Council provided states with extensive training in this regard. Nebraska developed a "Medicaid Impact Paper" for all of its screening programs. A new Nebraska Health Policy Academy was established to address access to health care.

Nebraska has focused on four discrete areas to build its skills and capacity in health reform. One, Nebraska convened a diverse group of public and private partners to develop a Community Health Worker (CHW) Curriculum based on the Massachusetts model. ACA defines CHWs as an EBI to better reach community members and improve health outcomes. Nebraska formed a Steering Committee because the possibility of including CHWs in ACA as a reimbursable service is being explored. The Steering Committee is charged with analyzing the scope, core competencies, roles and reimbursement strategies of CHWs. These efforts also led to the establishment of a CHW Association.

Two, Nebraska created a CHW Encounter Registry to capture and maintain community-based data reported by CHWs in the field, particularly the populations reached, community linkages and health outcomes. CHWs can use the web-based registry to document a number of patient variables (e.g., venues, demographics, modifiable lifestyle and risk behaviors, screening data, and community referrals and resources).

Three, Nebraska established Community Health Hubs to facilitate population-based screening. Program assets were mapped to document existing strengths, potential resources to provide to communities, and potential resources or expertise to leverage from partners. Support for and endorsement of the Community Health Hubs were solicited from partners and key stakeholders to ensure that these resources would meet the needs of communities and local agencies. Community Health Hub components that are being provided to communities include the CHW Curriculum, CHW Encounter Registry, financial resources, technical support, training and evaluation. The Community Health Hubs also are designed to leverage the expertise of internal and external partners and link local health departments, FQHCs and community resources.

Nebraska awarded funds to local health departments and FQHCs to complete specific activities for their respective Community Health Hubs, such as conducting environmental scans of communities and community-based resources, developing a community referral/resource directory, and identifying EBIs based on findings of the environmental scans. Nebraska also established certain cancer goals for the funded agencies to achieve (e.g., increase mammography rates in women 50-75 years of age, increase cervical cancer screening rates in women 21-65 years of age, and increase colon cancer screening rates in men and women 50-75 years of age).

Four, Nebraska implemented a comprehensive strategic planning process to remodel the current framework, policies and procedures of its cancer programs to meet new challenges in health reform. Efforts were made to identify current enrollees with new coverage though HIEs who no longer would be eligible for program services and current enrollees without insurance who might be able to obtain coverage. A commitment was made to adhere to U.S. Preventive Services Task Force (USPSTF) Grade A and B recommendations for preventive screening.

CDC guidance served as the foundation to educate all persons on health coverage benefits, provide referral and/or assistance to health insurance access, and evaluate individuals for their smoking status and referral to the Nebraska Tobacco Free Quitline. CDC's new data requirements for the WISEWOMAN Program were incorporated, particularly those that relate to capturing additional questions on personal history, modifiable risk factors and secondary risk reduction activities. Quality improvement activities were conducted to achieve an 80% colon cancer screening rate for program-eligible men and women.

Nebraska initiated the strategic planning process in November 2013 and began implementing the program remodel in July 2014. Over this timeline, Nebraska reviewed its existing forms and educational materials, updated the data system, redesigned screening cards and other program materials, offered provider training sessions, developed question/answer documents for various stakeholder groups, created flow sheets and checklists for staff, and launched a rapid-cycle "plan-do-study-act" model. Grand Rounds are now held on a monthly basis.

Nebraska developed specific screening pathways for two categories of patients. Program-eligible patients receive all services covered by NBCCEDP. Non-program-eligible patients receive referrals to a Community Health Hub, information on medication access, referral to the Nebraska Tobacco Free Quitline if needed, and education and materials on insurance coverage options.

Nebraska has made several accomplishments to date in its shift to a health reform environment. The CHW Encounter Registry is being utilized by two Community Health Hubs through workplace strategies and a community intervention focusing on Hispanic populations in faith-

based venues. Enrollment in the biannual CHW training class has continued to increase, but Nebraska plans to limit the class size to 26 students. Efforts are underway to identify resources to support Spanish-speaking CHW training classes.

Program data have been compiled from >3,200 Healthy Living Questionnaires to date: ≈30% of the patient population now has insurance and is ineligible for the program; 100% of men and women were evaluated for smoking and received information for the Nebraska Tobacco Free Quitline if needed; and 100% of men and women received information on enrolling in HIEs or education on their insurance benefits.

Massachusetts Experience

Felicia Solomon Tharpe, MPH
Public Health Advisor
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Ms. Tharpe described the impact of ACA on the Massachusetts BCC Program on behalf of Ms. Anita Christie, Program Director of the Women's Health Network Care Coordination Program. Massachusetts's overall breast cancer screening rate of ≈85% is much higher than the national rate of ≈72%. By race/ethnicity, breast cancer screening rates are highest in Hispanics (88%) and lowest in Asian Americans (≈73%). Massachusetts's high overall cervical cancer screening rate of ≈78% is slightly lower than the national rate of ≈80%, but the same disparities exist by race/ethnicity: highest in Hispanics (≈81%) and lowest in Asian Americans (67%).

Massachusetts's implementation of health reform in 2006 has resulted in insurance coverage rates of ≈98% of all children and ≈97% of all adults. Because Massachusetts is a Medicaid expansion state, an additional 45,000 low-income adults are now eligible for coverage. Moreover, the FPL was increased to 400% for subsidized coverage options. Individuals can more easily obtain insurance with a new streamlined application process.

Massachusetts routinely collects and publishes data on its health reform outcomes. An additional 440,000 residents have acquired insurance since health reform was implemented in 2006. The percent of non-elderly adults in Massachusetts who reported a usual source of care increased from 2006-2012: from 85% to 88% among all adults, from 79% to 82% among low-income adults at <300% FPL, and from 89% to 90% among adults with a chronic condition.

Increases also were observed in the percent of non-elderly adults in Massachusetts who received preventive care and other medical services in the prior year from 2006-2012: from 80% to 82% for any doctor visit, from 70% to 75% for a preventive care visit, from 66% to 70% for a dental care visit, and from 57% to 60% for prescription drug use.

Despite these achievements, challenges related to healthcare costs persist for low-income residents and persons receiving public insurance. Health reform in Massachusetts also has not meaningfully reduced the number of adults, including insured persons, who have significant out-of-pocket health expenses. A large percentage of residents were required to take actions to address healthcare-related financial problems, such as decreasing spending in other areas

(≈89%), using savings (≈77%), decreasing health care (≈51%), borrowing money or incurring credit card debt (≈41%), increasing work hours (≈35%), or declaring bankruptcy (≈4%).

Because Massachusetts has the highest healthcare costs of any state in the country, emphasis is now being placed on cost containment. Most notably, Massachusetts is targeting specific interventions to childhood asthma and three other chronic conditions that are known to increase healthcare costs as a result of emergency department visits and other issues.

Massachusetts's leadership at the state level in planning for health reform at the national level demonstrated that coverage would be expanded, the demand for clinical services would decrease, and the disconnect between payment for services and screening would persist, particularly disparities and barriers to access. Massachusetts convened a panel of 113 stakeholders to systematically identify gaps, strengths and added value of its screening programs. The panel submitted >200 recommendations to ensure that health reform would increase access to preventive services and address disparities.

Massachusetts used the panel's guidance as the basis to develop a new Care Coordination Program (CCP). Persons who are eligible for CCP include Massachusetts residents 40-64 years of age who are at <400 FPL. Minimum data element (MDE) inclusion criteria include uninsured females at ≤250% FPL. Massachusetts and CDC awarded funds to 11 clinical sites, including nine FQHCs, to implement CCP. The CCP sites have a total capacity to serve 12,000 women. In-reach to existing patient populations is the primary mechanism for client recruitment.

Clinical case managers provide case management to clients with abnormal screening results, while non-clinical patient navigators assist clients with barriers to receiving appropriate medical care. Patient navigators are required to complete a 14-week training course. In 2013, CCP screened 6,898 women. The 11 CCP sites have accounted for 24,724 patient navigation contacts over the past two years, including the navigation of 9,748 unique patients. Breast cancer screening (≈63%) and cervical cancer screening (≈19%) account for the vast majority of patient navigation calls.

Massachusetts piloted the new CBO-Community Linkages Project in 2013. The goal of this initiative is to link hardest-to-reach women with clinical services at the 11 CCP sites. Massachusetts launched a competitive process and awarded funds to three CBOs to target their respective high-risk populations: African immigrants in Boston, Hispanics in Framingham, and Hispanics and women with mental health issues in Springfield. The CBOs use CHWs to provide screening education to women and refer eligible women to one of the 11 CCP sites for patient navigation.

Massachusetts is providing extensive TA to the CBOs to resolve numerous problems that were identified during the pilot: Institutional Review Board (IRB) issues, inappropriate screening ages of women, refusals to give written consent for program participation, staff turnover, cultural differences among populations, delays in program implementation, improper translation of educational materials for the target populations, and incomplete collection of screening data.

Overall, Massachusetts has faced a variety of challenges in implementing health reform over the past eight years. The NBCCEDP 60/40 requirement limits the ability of the BCC Program to dedicate staff, time and funding to non-screening components. Dual data entry by clinical sites for electronic medical records (EMRs) and NBCCEDP reporting requirements has decreased the accuracy of data. Massachusetts developed a web-based HL7 platform to mitigate the need

for dual data entry, but infrastructure issues at the state health department has not allowed for implementation of this system.

Clinical sites are not given payment or other incentives to collect and submit data on clinical services. Unlike the BCC Program, Massachusetts's non-clinical patient navigation model is unable to comply with CDC's requirement for programs to collect and report MDEs. State budget cuts, staff turnover, new management and other organizational issues must still be addressed in a health reform environment. As the first state with experience in implementing health reform, Massachusetts has continued to be responsive to and serve as a leader for other states in terms of sharing models and lessons learned.

North Carolina Experience

Marcus Plescia, MD, MPH
Director, Mecklenburg County Health Department

Dr. Plescia described the impact of ACA on the North Carolina BCC Program. One, North Carolina is addressing ACA-related challenges at the state level. The North Carolina Institute of Medicine has published a series of reports over the past six years to examine the potential implications of ACA on the state. North Carolina accounts for 409,683 uninsured adults 19-64 years of age who are at <100% FPL. These individuals will continue to have no access to health insurance without Medicaid expansion. However, some adults at 100%-400% FPL will have opportunities for coverage through HIEs.

Rural counties in North Carolina account for the largest numbers of uninsured persons who are potentially eligible for and would benefit most from HIE subsidies. However, the most densely populated counties (e.g., Mecklenburg and Wade Counties) will account for the largest insured populations.

Because advocates have been unsuccessful in passing legislation for North Carolina to become a Medicaid expansion state, efforts are being targeted to providing coverage to uninsured persons at 100%-400% FPL through HIE subsidies. North Carolina is the 10th most populous state in the nation, but is the 5th most successful state in enrolling persons in HIEs. North Carolina also will continue to target its Medicaid funding to serving the significant proportion of uninsured women who need access to BCC screening.

Two, North Carolina is addressing ACA-related challenges at the local level. Newly insured patients at the county level have not been identified to date. Mechanisms for counties to serve new patient populations have not been determined. State and federal public health leadership has been unable to provide local health departments with specific guidance on redesigning their BCC Programs for a health reform environment due to competing priorities.

North Carolina has considered several options to build health reform capacity at the local level. For example, CDC and HRSA should compile and widely disseminate experiences and lessons learned by local health departments in implementing the Ryan White HIV/AIDS Program under ACA. Because Ryan White also targets uninsured, low-income patient populations, these strategies could easily be adapted for BCC Programs. Moreover, local health departments

could play a much greater role in population-based cancer screening, particularly in Medicaid-expansion states.

Three, North Carolina is addressing ACA-related challenges in terms of disparities in BCC screening. Limited access to care and historical mistrust of government initiatives continue to serve as barriers to outreach, particularly in African American communities in the South. North Carolina acknowledges that local health departments will play a critical role in overcoming these barriers in a health reform environment.

Four, North Carolina is addressing ACA-related challenges in terms of changes in Medicaid. Children and adults with significant co-morbidities account for the vast majority of the Medicaid population in North Carolina. Although North Carolina is not a Medicaid expansion state, efforts are underway to develop a strong network of Medicaid providers to serve the new population of relatively healthy adults who do not have expensive co-morbidities. CDC should advise all of its BCC Programs to place more emphasis on this new Medicaid population.

Connecticut Experience

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health

Dr. Mullen described the impact of ACA on the Connecticut BCC Program. Over the one-year period from August 2013 to August 2014, enrollment in ACA health insurance plans resulted in an overall reduction of 48.5% in the number of new and returning clients to the Connecticut BCC Program. Similar declines were observed by race/ethnicity: a 48% reduction among African American women, a 47% reduction among white women, and a 33% reduction among Hispanic women. Connecticut was required to return a portion of its FY2014 BCC funding to CDC due to the inability to meet the projected target for the number of women screened.

Connecticut was informed by its provider network that some women intend to incur a penalty in the future rather than reenroll in ACA health insurance plans. Women with coverage under ACA who were screened at no cost faced new out-of-pocket expenses for diagnostic testing deductibles.
Connecticut plans to focus on several issues to emphasize the continued need for BCC Program funding, resources and support. These initiatives include care coordination activities, health reform transformation opportunities, an evidence-based CHW program and curriculum, and strategies to address persistent disparities in rural areas of the state. Connecticut also will review the Massachusetts and Nebraska models to improve patient navigation for its population of newly insured women.

Connecticut has achieved a number of successes in health reform to date. Connecticut extensively engaged its FQHCs at the outset of ACA to provide direct services to patients, while building a population-based system. Connecticut developed its State Health Improvement Plan with two indicators to increase BCC screening rates. These indicators are stratified by race/ethnicity to track statewide progress in addressing disparities over time.

BCCEDAC suggested three areas in state BCC Programs that CDC should consider for scale-up at the national level in a health reform environment.

- CDC should provide all BCC Programs with the recent evidence review and upcoming recommendations by the *Guide to Community Preventive Services* on the use of CHWs to promote health and preventive screening measures.
- CDC should replace NBCCEDP's current volume-based reimbursement metrics with quality and service indicators for the proportion of the population reached.
- CDC should ensure that the Massachusetts CBO-Community Linkages Project is available for adaptation by all BCC Programs after problems with the pilot are resolved. The project is designed to link hardest-to-reach women with clinical services and particularly would help CBOs in implementing cost-effective strategies to reach immigrant women from countries with no cervical cancer screening programs. However, CDC should first conduct a study to determine the feasibility of adapting this initiative for various cultures and languages.

PANEL PRESENTATION: CDC'S POPULATION-BASED ACTIVITIES TO INCREASE APPROPRIATE SCREENING AMONG WOMEN

A panel of speakers presented CDC's population-based activities to increase appropriate cancer screening among women. The overviews are summarized below.

NBCCEDP-Medicaid Demonstration Projects

Frank Bright, MS
Senior Public Health Advisor for Cancer
National Association of Chronic Disease Directors

Mr. Bright presented an overview of the NBCCEDP-Medicaid Demonstration Projects. The National Association of Chronic Disease Directors (NACDD) has awarded CDC funding to BCC Programs in nine states to date to conduct this initiative: Indiana, Michigan, Mississippi, North Carolina, Nevada, New York, Oregon, Utah and Washington. The remaining 58 BCC Programs will be eligible for funding in the future.

The purpose of the demonstration projects is two-fold. First, grantees formed partnerships with Medicaid agencies to develop and implement plans to transition women screened in BCC Programs to Medicaid as progress is made on ACA and Medicaid expansion. Second, grantees will assure that at least the same quality of care is provided to women screened in BCC Programs. Preliminary accomplishments of select states to date in the demonstration projects are summarized below.

Michigan convened an inaugural meeting with a diverse group of state and local stakeholders, met with relevant Medicaid staff to review and discuss expansion information, and used Medicaid health information technology (HIT) to incorporate BCC data into the Medicaid data warehouse. This effort will allow Michigan to match its data with Medicaid records, cancer registry and immunization data, and practice-based EMRs in the future.

A partnership was established with the Michigan Primary Care Association to improve breast, cervical and colorectal cancer screening rates and increase HPV vaccination rates in FQHCs. Under a competitive FOA, $15,000 grants were awarded to four FQHCs in Michigan to implement EBIs to increase cancer screening and HPV vaccination rates. The Michigan FQHCs documented a number of successes.

An FQHC established partnerships with CBOs to increase cancer awareness and prevention in their communities. CBO volunteers directly contacted clients to provide education on the importance of preventive care and screening reminders. An FQHC made reminder calls to patients that significantly decreased the "no-show" rate for mammogram appointments from 60% to 33% over a six-month period. An FQHC devoted a great deal of time to refining programmatic processes due to complexities identified in its existing colorectal cancer screening tracking system. An FQHC successfully increased the percentage of female patients with documented cervical cancer screening in EMRs by 15% to the project goal of 45%.

Nevada entered into a memorandum of understanding with Medicaid, participated in monthly TA calls with NACDD, hired a contractor to meet the design and data requirements of the demonstration project, and identified key staff, agencies and potential partners.

Nevada developed roadmaps and algorithms to achieve three key goals. First, cancer screening would be increased among never or rarely screened populations. Second, a combination of NBCCEDP and Medicaid datasets would be used to sustain appropriate cancer screening and follow-up for current BCC Program enrollees who would transition to Medicaid services. Existing data systems would be enhanced or combined to support population-based education, outreach, screening and follow-up.

Nevada is implementing its demonstration project in four phases. Phase 1 focuses on integrating Medicaid data into the Nevada Cancer System and Tracking (CaST). The data interface will be used to obtain baseline screening rates, track screening utilization among the Medicaid target population, and monitor clients who have transitioned from the Women's Health Connection (WHC) Program to Medicaid.

Methods will be designed to transfer data from the Medicaid data warehouse and CaST data system. Specialized software will be developed to analyze targeted Medicaid claims and demographic data through enrollment, ICD-9 and CPT code data. A system will be created to produce rescreening notices for Medicaid clients based on USPSTF screening guidelines. Nevada expects to complete the phase 1 activities by June 30, 2015.

Nevada generated preliminary results of the demonstration project based on Medicaid enrollment data for women 40-64 years of age who were enrolled in ACA in the six-month period of January 1, 2014-June 27, 2014. All claims were associated with enrollment records. A new CaST record was created for all Medicaid enrollments. Medicaid claim lines were filtered by breast cancer, cervical cancer or HPV screening CPT and ICD-9 codes. Medicaid claims linked to CaST enrollments and screening cycles were created as well.

- 37,378 women were enrolled over the six-month period.
- 5,156 Medicaid clients transitioned from WHC to Medicaid.
- 32,226 new Medicaid clients were added to CaST.

- 1,738 new Medicaid clients were screened for breast cancer, cervical cancer and HPV, while 30,488 women have not been screened since their enrollment in Medicaid.
- 234 women had abnormal breast cancer screening results; 83 women had abnormal cervical cancer screening results; and 7 women had positive HPV results.

Washington applied for funding to transition eligible clients into expanded Medicaid and also to explore the feasibility of building a statewide screening registry. Washington initiated preliminary activities in 2001 to determine whether these goals could be achieved. Efforts were made to upgrade the existing HIT system to assist with identifying and transitioning eligible persons to Medicaid. The feasibility of redesigning the HIT system as an HL7-ready HIE standard was explored to facilitate the collection of cancer screening data from non-BCC Program providers.

HIE staff extensively discussed the possibility of linking the HIT system with other provider systems to build a statewide screening registry. A collaborative workgroup of key partners was convened to share the outreach, recruitment and enrollment expertise of the BCC Program, identify shared goals, and plan for Medicaid expansion in the future.

Washington found that its existing HIT system was not capable of serving as a statewide screening registry. HIE staff was unable to support and prioritize the screening registry project in the near future. The BCC Program did not have sufficient capacity to manage incoming data from multiple providers.

Washington is undertaking efforts at this time to overcome these barriers. An all-payer statewide claims database will be built as part of the State Health Care Innovation Plan. The populated database will facilitate the availability of statewide cancer screening rates. Search criteria by provider name and type, county, region, insurance plan and other variables will inform targeted outreach, recruitment and screening education activities.

Washington currently is implementing three pilot projects to achieve key goals. Creative strategies are being developed and tested to identify and reach the new at-risk population of uninsured persons at 139%-250% FPL. Assistance is being provided to clients and non-clients to transition into the state Medicaid program or an ACA qualified health plan. Program policies are being refined to increase the quality of screening, diagnosis and treatment to support changes in health reform.

Washington enhanced its existing HIT system with new tracking capabilities to identify and generate reports of low-income clients who need rescreening. Robust case management tracking screens may be used for clients both within and outside of the BCC Program. This feature has the capability to produce standardized reports.

New York applied for funding due to an increase of newly insured persons through ACA and the state as well as the acknowledgment that breast, cervical and colorectal cancer screening are covered benefits. New York plans to utilize its funding to support collaboration among state public health, Medicaid and external partners; identify opportunities to increase screening rates and decrease disparities; and implement a partnership model to improve the delivery of care.

New York has conducted several activities since its planning grant was awarded in March 2013. Data from the Healthcare Effectiveness Data and Information Set were compiled. A meeting was held with health plan medical directors and a health plan survey was administered. A

summary report was produced based on outcomes of a meeting with state Medicaid managed care plans. The need for focused efforts was emphasized. After the implementation grant was awarded, partners in Western New York were engaged to review findings, identify needs and explore improvement opportunities.

New York plans to focus on several areas that will require action and collaboration. Regions of the state with low cancer screening rates will be determined. A survey will be administered to Medicaid enrollees to identify barriers to not receiving screening. Information on EBIs will be disseminated. A compendium of local cancer screening resources will be developed and widely distributed. A quality improvement (QI) consultant will be engaged to inform improvement activities.

New York State Innovation Project with Federally Qualified Health Centers

Teri Larkins, PhD
Public Health Advisor, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Dr. Larkins presented the results to date and future direction of the New York State (NYS) Innovative Cancer Screening Registry Grant. The Community Health Care Association of NYS (CHCANYS) represents 63 FQHCs across ≈500 sites and serves 1.4 million persons annually. Low cancer screening rates have been reported in patient populations served by these FQHCs: a 60% breast cancer screening rate, a 78% cervical cancer screening rate, and a 48% colorectal cancer screening rate. Most patients are uninsured or covered by Medicaid and are minorities or recent immigrants.

Several goals were established for the innovation project. The cancer screening registry will be designed to automate provider assessment and feedback on screening and monitoring of screening results; assure adherence to evidence-based guidelines for cancer screening; and accurately target EBIs to practices and communities with low cancer screening rates. An existing HIT infrastructure will be utilized to build the cancer screening registry. Efforts also will be targeted to the early detection of 115 breast, cervical and colorectal cancers each year.

The capacity of NYS FQHCs will be improved in delivering quality preventive care for breast, cervical and colorectal cancers. At least 75% of FQHCs that are CHCANYS members will be enrolled in the provider assessment and feedback system by year 4. Breast, cervical and colorectal cancer screening rates will be increased by 5% over baseline by the end of year 5. CHCANYS will develop and house the cancer screening registry, while the Island Peer Review Organization will conduct the program evaluation.

A uniform web-based data system will be used to collect data from EMRs and other sources to create an integrated database for enhanced analysis and reporting. A dashboard will be generated for providers to compare their performance to other practices and benchmarks based on 42 key chronic disease quality indicators and 7 cancer screening, follow-up and treatment measures. Data analyses will be possible at FQHC, clinic and provider levels. A logic model with inputs, activities, outputs and outcomes will serve as a roadmap for the project.

A tremendous amount of progress has been made to date in the innovation project. Of 63 NYS FQHCs, 34 were connected to the cancer screening registry with 8 different EMR systems. Cohorts 1 and 2 include 24 FQHCs that represent >600,000 patients. Metrics for cancer screening that are endorsed by the National Quality Forum were developed and validated. An environmental scan will be performed, a literature review will be conducted, and an expert panel will be convened to develop metrics for cancer treatment and follow-up. The cancer screening registry was enhanced with a new Patient Visit Planning Report and Referral Management Tool to further support population-based patient management.

A survey was administered to the first cohort of 12 FQHCs to assess their baseline HIT functional status and QI organizational status. Of these FQHCs, 79% had reached or were in the process of reaching level 3 of the Patient Centered Medical Home certification process; 75% had dedicated at least a half-time equivalent position to Meaningful Use adoption; and 75% had developed a QI work plan that is updated annually.

Data reported in practice site EMRs were compared to data collected by the cancer screening registry to complete data validation for 24 FQHCs in cohorts 1 and 2. A review was performed on a random sample of 30 patient records per site for each of the three cancer screening metrics. Data validation was undertaken to improve the accuracy of information reported to the cancer screening registry and also to identify both high and low performing sites. Each FQHC in cohort 1 received a data validation report that summarized their individual data quality issues, potential data mapping errors and other findings.

A survey was administered to assess workflow processes of the FQHCs and create a model workflow process. The template will provide FQHCs with best practices on the use of cancer screening policies, patient flow, use of provider alerts and other electronic tools, and patient tracking, monitoring and follow-up.

Feedback from the FQHCs, outcomes of the data validation process and other factors led to the implementation of recommendations to improve data quality and clinical workflow processes: remove non-primary care providers from the cancer screening registry, document system-wide issues and resolutions, identify and consistently use structured fields, update the list of codes, and correct the FQHC workflow and data entry errors.

A Learning Collaborative was established in January 2014 to provide FQHCs with TA, training, best practices and other resources over a 12-month period. FQHCs are given opportunities to participate on webinars, bimonthly calls, in-person workshops and learning sessions to increase their breast, cervical and colorectal cancer screening rates by at least 5% over baseline. The first cohort of 12 FQHCs achieved data quality and clinical workflow improvements as part of the first QI Learning Collaborative.

An Evidence-Based Change Package was developed based on a systematic literature review. The change package outlines best practice strategies in four broad categories: cancer screening policies, provider recommendations, practice reminder systems, and patient tracking and monitoring. Plans are underway to develop and implement an evaluation plan for the Learning Collaborative. FQHCs and practice sites that increase their cancer screening rates by ≥10% for one or more cancer metrics will provide key outcome measures to assess the effectiveness of the Learning Collaborative.

Results of the data validation and workflow processes as well as the needs of individual FQHCs were compiled to prioritize improvement opportunities and establish screening goals. Increases in aggregate screening rates for all three measures were reported for the first cohort of FQHCs from December 2013 to September 2014: from 39% to 44% for breast cancer screening, from 48% to 51% for cervical cancer screening, and from 28% to 46% for colorectal cancer screening.

The next steps in the innovation project will be to develop, test and pilot metrics for cancer follow-up, continue to evaluate Learning Collaborative outcomes for FQHCs in cohort 1, initiate project activities with FQHCs in cohorts 3 and 4, administer a staff perception and burden survey, widely disseminate the model workflow process, and assess utilization of cancer screening registry data to improve clinical outcomes. NYS is requesting guidance at this time from CDC, BCCEDCAC and other experts on providing external QI support, best practices and other resources to practices.

Minnesota Innovation Project with Medicaid

Valerie Richmond-Reese, MSW
Public Health Analyst, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Ms. Richmond-Reese presented the Minnesota Innovation Project with Medicaid. Minnesota was awarded five-year funding by NCI in 1998-2003 to conduct a randomized controlled trial to increase mammography use. The study showed that direct mail alone, direct mail and patient navigation, and direct mail with a reward were effective strategies to recruit women for NBCCEDP. Patient navigation significantly increased breast cancer screening, while the provision of rewards tripled effectiveness. NCI incorporated this evidence-based strategy into its Research Tested Intervention Program, but the approach has not been tested for cervical or colorectal cancer screening.
Data show that breast, cervical and colorectal cancer screening rates in Medicaid populations are substantially lower than those for privately insured persons. Cancer survival rates in Medicaid populations are equivalent to or worse than those for uninsured persons regardless of race/ethnicity.

The goal of Minnesota's current project with CDC is to develop and implement an innovative, cost-effective approach to increase breast, cervical and colorectal cancer screening rates in the statewide Medicaid population. The effectiveness and cost-effectiveness of direct mail with rewards will be tested in the priority populations of Medicaid enrollees who are unscreened, women 40-74 years of age for breast cancer screening, men and women 50-74 years of age for colorectal cancer screening, and persons overdue for screening.

Minnesota's patient navigation services include motivational interviewing, patient education, counseling on barriers, identification of nearby clinics, appointment scheduling, multilingual staff, interpreter and translation services, and transportation. The components of the intervention include compiling claims data to identify unscreened Medicaid enrollees, sending direct mailings to the priority populations, requiring participants to complete screening within one year of

receiving the invitation, and reviewing Medicaid claims data to verify completion of screening prior to sending the financial reward.

Minnesota designed the evaluation with a post-test randomized to an intervention group and a control group that will receive the intervention six months later. Based on the evaluation design, cancer screening rates are expected to be higher in the intervention group than those in the delayed control group. Minnesota's accomplishments to date in its innovation project are summarized below.

Direct mailings were completed for priority populations that need breast and colorectal cancer screening (or an estimate of 66,882 individuals). As of October 20, 2014, 1,039 appointments were scheduled (or a response rate of ≈2.4%). Key relationships were established with the state Medicaid program, state health plans, the state health department and a large health system. Interagency data-sharing agreements were developed and approved. A logic model, evaluation plan, patient navigation training procedures and protocols, and a system to track calls and schedule appointments were developed.

Breast and colorectal cancer screening intervention materials were created. A feasibility study was piloted. Data elements were identified to collect Medicaid claims data and demographic data on the target populations. Barriers to implementing the project were resolved, such as turnover of key staff, CDC's approval of a $15 reward rather than the $20 reward originally proposed in the application, an unexpected IRB review that delayed access to Medicaid data, and bureaucratic issues with the interagency data-sharing agreements.

Minnesota's next steps are to obtain up-to-date addresses for direct mailings that were returned, initiate the review of Medicaid claims data to verify completion of screening, and develop and disseminate a detailed protocol and guidebook based on results of the project. Minnesota recognizes the wide variation in Medicaid among states due to differences in the population's disability status, access to care, language and cost-sharing practices.

Dr. Sabrina Matoff-Stepp is the *ex-officio* member for HRSA. She provided additional details on the role of FQHCs in increasing population-based screening. Based on HRSA's 2013 Uniform Data System (UDS) performance measures, the cervical cancer screening rate has remained relatively stable at 57%-58% over the past three years. HRSA commissioned the National Academy of State Health Policy to identify barriers to cervical cancer screening in FQHCs. The most common problems reported by FQHCs included limited access, insufficient resources, system-level issues, quality challenges, and new requirements for coordinated or patient-centered care.

The 2013 UDS performance measures also showed low breast cancer screening rates (e.g., ≈471,000 patient visits for breast cancer screening out of a total of >21 million patient visits to FQHCs). HRSA is now making efforts to compile best practices and lessons learned from high performing FQHCs with documented success in meeting or exceeding Healthy People 2020 goals. Dr. Matoff-Stepp encouraged the BCCEDCAC members to visit the HRSA.gov website to obtain more information on UDS performance measures that FQHCs are required to collect and submit to HRSA annually.

BCCEDCAC discussed the following topics with the panel on population-based activities to increase appropriate cancer screening among women.

- Costs for the NYS FQHCs to sustain the innovation project over time after the funding cycle ends.
- A comparison of the cost of the innovation project for CHCANYS and non-CHCANYS members.
- The feasibility of using NYS Cancer Screening Registry data for chronic conditions other than cancer.
- The need to use the NYS innovation project as a model to shift from volume- to value-based screening.
- Minnesota's plans to include a follow-up component in its innovation project, particularly for women with abnormal screening results.
- Differences between mandates, appropriations and other aspects of the CDC Colorectal Cancer Control Program and NBCCEDPP.

BCCEDCAC Moderated Discussion

Stephen Taplin, MD, MPH
Chief, Process of Care Research Branch
National Cancer Institute, National Institutes of Health
BCCEDCAC *Ex-Officio* Member

Dr. Taplin moderated a discussion for the BCCEDCAC members to offer guidance to CDC on NBCCEDP's role in helping providers to make appropriate risk assessments and utilize shared decision-making tools. Comments and suggestions by the members are outlined below.

- NCI currently is funding several activities to develop standards for providers to establish and stratify risk. CDC should consult with Dr. Taplin to explore partnership and funding opportunities with NCI in these initiatives.
- Efforts to give providers generalized, population-based recommendations will be extremely difficult due to the heterogeneity of cancer.
- Providers will view risk stratification as a significant burden during the patient visit due to time constraints in their practices. To overcome this challenge, CHWs and patient navigators should be trained to complete risk assessments before patients present to providers. This approach would facilitate more meaningful provider-patient dialogue and promote patient-centered care. A pilot study should be conducted to assess the feasibility of this strategy.
- DCPC's previous materials on shared decision-making in cancer should be updated, evaluated and disseminated to both providers and women as web-based tools. These resources could assist providers in interpreting and better explaining risk to patients.
- Representatives of affected populations should be extensively engaged in developing, testing and piloting risk communication messaging.
- An ethical approach should be taken to identify, reach and target messaging to the priority population of high-risk women who have the greatest need for screening. This goal could be achieved by training CHWs to properly collect samples from women for submission to a centralized testing laboratory. Outreach efforts could then be devoted to the smaller population of women with positive or abnormal screening results, particularly for cervical cancer screening.

Dr. Taplin concluded the discussion by noting BCCEDCAC's general agreement for CDC to devote resources to conducting a systematic literature review to better understand risk. The literature review should facilitate the development and dissemination of risk assessment and shared decision-making guidance, tools and resources to providers and women.

Public Comment Session

Ms. Blackmon opened the floor for public comments; no participants responded.

With no further discussion or business brought before BCCEDCAC, Ms. Blackmon recessed the meeting at 4:40 p.m. on November 6, 2014.

Opening Session: November 7, 2014

Jameka R. Blackmon, MBA, CMP
Public Health Advisor, Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
BCCEDCAC Designated Federal Officer

Ms. Blackmon conducted a roll call and announced that the 17 voting members and *ex-officio* members in attendance constituted a quorum for BCCEDCAC to conduct its business on November 7, 2014. She called the proceedings to order at 9:02 a.m. and welcomed the participants to day 2 of the meeting. None of the voting members publicly disclosed conflicts of interest for any of the published agenda items.

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Chair

Dr. Mullen thanked the BCCEDCAC members for their robust discussion and thoughtful insights on day 1 of the meeting. She also commended the day 1 speakers on their presentations that documented the ongoing success of NBCCEDP. She was confident that health reform would provide new opportunities to remove historical barriers and make NBCCEDP even stronger than in the past.

Dr. Mullen urged the BCCEDCAC members to become change agents at state, local, program and community levels to promote health transformation. Most notably, public health should shift its focus from specific cancer risk factors to social determinants that cut across all diseases and populations. NBCCEDP should play a strong role in delivering direct services and creating a context for persons to access individualized care. Dr. Mullen asked BCCEDCAC to consider these issues in preparation of proposing formal recommendations to CDC on the future direction of NBCCEDP in a health reform environment.

PANEL PRESENTATION: IMPLICATIONS OF ACA ON THE NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM

Jacqueline Miller, MD, Capt. USPHS
Medical Officer, Program Services Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Dr. Miller introduced a panel of speakers to describe the implications of ACA on various components of NBCCEDP. The overviews are summarized below.

ACA Impact on Traditional NBCCEDP Policies

Analía Stormo
Public Health Consultant
National Association of Chronic Disease Directors

Ms. Stormo described the impact of ACA on traditional NBCCEDP policies. CDC will monitor the impact of ACA on state BCC Programs by collecting data in a more systematic and consistent manner than in the past. A key provision was incorporated into ACA to establish a Health Insurance Marketplace. A streamlined application process allows eligible consumers to enroll in expanded Medicaid or qualified health plans. The Marketplace determines whether the consumer would be eligible for health plan subsidies, such as reduced cost-sharing of co-pays and deductibles or discounted premiums through premium tax credits.

ACA includes an Essential Health Benefits Package that requires all qualified health plans and expanded Medicaid programs to cover a comprehensive set of services. Certain preventive services, including BCC screening, must be covered in their entirety without co-pays or deductibles. As of June 2014, 27 states have implemented Medicaid expansion, 21 states have no plans at this time to implement Medicaid expansion, and 3 states are still considering Medicaid expansion. To date, 27 states have adopted a federally-facilitated Marketplace, 17 states have adopted a state-based Marketplace, and 7 states have adopted a federal-state partnership Marketplace.

Various types of insurance affordability programs are available through the Marketplace. BCC Programs are facing three different scenarios because states are allowed to opt-in or opt-out of Medicaid expansion. Scenario 1 is an option for Medicaid expansion states. Persons at 138% FPL are eligible for Medicaid expansion and are routed to the Medicaid enrollment process that varies across states. Persons who are not eligible for Medicaid expansion are assessed to determine their eligibility for subsidized coverage. Persons at 139%-250% FPL are eligible for cost-sharing reductions, while persons at 139%-400% FPL are eligible for premium tax credits.

Scenario 2 is an option for non-Medicaid expansion states. Only persons at >100% FPL are eligible for subsidized Marketplace coverage. This scenario has resulted in a coverage gap in non-Medicaid expansion states. Persons do not meet eligibility criteria to receive services from traditional Medicaid programs, but their incomes are not sufficient to receive subsidies and purchase coverage from qualified health plans in the Marketplace. Persons in the coverage gap

are expected to remain uninsured. NBCCEDP will continue to provide screening for eligible women at ≤250% FPL.

The coverage gap varies among non-Medicaid expansion states due to differences in income eligibility criteria for traditional Medicaid services. For example, the coverage gap in Alaska is significantly smaller than in Alabama. At the national level, 4.8 million uninsured non-elderly adults below the FPL fall into the coverage gap. Of the national population in the coverage gap, 79% reside in the South with Texas accounting for 22%, Florida accounting for 16% and Georgia accounting for 8%.

Scenario 3 is an option for states that are expanding Medicaid through premium assistance. This option allows states to use their Medicaid funds to purchase insurance coverage though the Marketplace for persons who otherwise would be eligible for expanded Medicaid. HHS guidance states that premium assistance enrollees will continue to be Medicaid beneficiaries and entitled to all benefits, including non-emergency transportation and other "wraparound" services. Because the provision of wraparound services is at the discretion of each state, the ability of persons enrolled in the premium assistance model to successfully access health services is questionable.

CDC is continuing to make strong efforts to address questions and concerns by grantees on the identification of NBCCEDP-eligible women in a health reform environment. CDC used the three scenarios of Medicaid expansion, non-Medicaid expansion and premium assistance as a starting point to draft messages for grantees and clarify or revise existing NBCCEDP policies. CDC provided clear guidance to grantees for two NBCCEDP populations.

For the uninsured population, grantees were advised to evaluate the insurance status of women prior to each clinical visit, including a reassessment of insurance status at the time of diagnostic or follow-up testing. Grantees were advised to establish a referral process to the Marketplace to identify women who would be eligible for expanded Medicaid or subsidized Marketplace coverage.

Grantees in Medicaid expansion states were advised to refer all women at 0%-250% FPL to the Marketplace. Grantees in non-Medicaid expansion states were advised to refer only women at >100% FPL to the Marketplace to determine their eligibility for Marketplace coverage and also to address the coverage gap. Grantees in non-Medicaid expansion states with restrictions on referring women to the Marketplace were advised to document these cases. Because HIEs and BCC Programs are unique in each individual state, grantees were advised to closely collaborate with Marketplace staff or other state partners to make referrals.

CDC will begin collecting NBCCEDP data in a more systematic and consistent manner in response to HHS's request to closely monitor the impact of ACA on state BCC Programs. To support this goal, grantees were advised to obtain a complete MDE record for each woman who received at least one NBCCEDP test or procedure even if health insurance was subsequently purchased for diagnostic and follow-up testing. These data will be used to monitor referrals to the Marketplace.

Grantees were advised to collect additional data on the uninsured population: (1) the number of women who received an NBCCEDP-funded clinical test or procedure and subsequently were referred to the Marketplace for assessment of insurance eligibility and (2) the number of referred women who returned to the BCC Program after at least 12 months and were still uninsured.

For the underinsured population, grantees still have the flexibility on whether to serve these women. As the payer of last resort, NBCCEDP may pay for co-pays or deductibles if women are unable to afford these costs. The determination on whether co-pays or deductibles serve as a financial barrier for women to obtain services is at the discretion of each individual BCC Program, but payments by grantees cannot exceed the Medicare reimbursement rate. CDC funds can only be used to pay the lower amount if the co-pay or deductible is lower than the Medicaid reimbursement rate. Grantees were advised to clearly define policies on eligibility criteria and share these requirements with CDC.

Grantees were advised to obtain a complete MDE record for each woman for whom NBCCEDP funds were used for payment of co-pays or deductibles. Grantees were advised to initiate a more consistent process of documenting the percentage of underinsured women who received an NBCCEDP-funded clinical test or procedure within a program year.

ACA Impact on the 60/40 Requirement

Mike Mizelle
Associate Director for Policy
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Mr. Mizelle described the impact of ACA on the 60/40 requirement. NBCCEDP legislation mandates the use of at least 60% of federal funds for direct screening services, including case management. Because NBCCEDP authorization expired in 2012, CDC has explored several options to modify the existing legislation and provide grantees with greater flexibility in a health reform environment.

New language to eliminate the 60/40 requirement could be included in an NBCCEDP reauthorization bill passed by Congress, but CDC does view this option as viable in the current political climate. A new appropriations bill would be a much easier option. Most notably, the Senate proposed new bill language to eliminate the 60/40 requirement in both the FY2014 and FY2015 appropriations. The House did not agree to the proposed Senate bill and asked CDC to conduct a survey to determine the number of grantees that would exercise greater flexibility if Congress made this option available.

CDC developed a report that will be submitted to the Congressional Appropriations Committee after its internal clearance process is complete. The report documents the survey results that showed 63 of 67 BCC Programs would take advantage of greater flexibility. The report also highlights new opportunities that would be available to grantees if the 60/40 requirement was eliminated. CDC hopes the report will encourage the House to agree to the proposed Senate bill. The FY2014 President's budget also included a request for appropriations language to eliminate the 60/40 requirement.

ACA Impact on Patient Navigation and Education Practices

Amy DeGroff, PhD, MPH
Program Evaluator
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention

Dr. DeGroff described the impact of ACA on patient navigation and education practices. Multi-level barriers to cancer screening are well documented in the literature, including those at individual, cultural, environmental and system levels. Patient navigation is designed to address these barriers and is viewed as a patient-centric approach.

In terms of implementation, several professional societies have reached consensus on and adopted the definition of "patient navigation" as individualized assistance to patients, families and caregivers to help overcome healthcare system barriers and facilitate timely access to quality health and psychosocial care across all phases of the cancer continuum of care: screening, detection, diagnosis, treatment and end-of-life.

Various components can be included in a patient navigation model, but the needs of the target population should serve as the foundation to design the program. These components include a theoretical framework, program goals, community characteristics, points of intervention within the cancer continuum, setting for service delivery, the range of navigation services provided, qualifications of navigators, communication methods, navigator training and supervision, and monitoring and evaluation.

In terms of the state of the science, the existing patient navigation evidence base includes two reviews of the published literature. The 2008 Wells, *et al.* study reviewed 16 articles with efficacy data and reported improvement in three areas due to patient navigation: screening adherence rates for breast, cervical and colorectal cancers with a range of 10.8% to 17.1%; adherence rates for diagnostic follow-up with a range of 21% to 29.2%; and timeliness to diagnostic resolution.

The 2011 Paskett, *et al.* study reviewed 17 articles with efficacy data and reported improvement in only one area due to patient navigation: screening adherence rates for breast, cervical and colorectal cancers with a range of 31% to 59% for mammography screening. The review of one study did not provide evidence of improved timeliness of diagnostic resolution. Limitations of both the 2008 and 2011 literature reviews included variations in study designs and methodologies as well as multi-component interventions that did not allow conclusions to be reached on the efficacy of patient navigation.

Data are continuing to be published from the Patient Navigation Research Program (PNRP) that NCI funded in 2005-2010. PNRP served as the first comprehensive, multi-site efficacy study on patient navigation. The study was conducted at nine U.S. sites to determine the role of patient navigation in two key outcomes: timely diagnostic resolution and timely initiation of cancer treatment.

The 2014 Battaglia, *et al.* study documented the PNRP findings and concluded that patient navigation is effective overall. However, patient navigation was found to be most useful in three

areas: (1) settings with low resources; (2) settings with large patient populations requiring follow-up or treatment based on abnormal screening results; and (3) settings with underserved populations at risk of being non-compliant or lost to follow-up.

The combined analysis of all nine PNRP sites showed a modest, but statistically significant benefit for both outcomes from 91 to 365 days of observation. No benefit from patient navigation was observed during the first 90 days. The results of analyses of individual sites greatly varied.

- Patient navigation had an impact on timely diagnosis of breast cancer at 5 sites with the largest difference reported at ≈20%; 2 sites reported no impact.
- Patient navigation had an impact on timely diagnosis of cervical cancer at 2 sites with the largest difference reported at ≈20%; 2 sites reported no impact.
- The impact of patient navigation was greatest at sites with low baseline rates for diagnostic resolution or treatment initiation in the control arms.
- A ceiling effect was observed when the control arms had timely diagnostic resolution of ≥90% at year 1.

In terms of research translation, the *Community Guide* does not recommend patient navigation as a standalone intervention at this time, but navigators are viewed as a mechanism to deliver other EBIs (e.g., providing one-on-one education and reducing structural barriers). Discussions, reviews and revisions of multi-component strategies for the *Community Guide* are underway to facilitate a better assessment of patient navigators and CHWs. Due to the existing patient navigation evidence base and the broad use of this strategy in public health, CDC and its partners are exploring options for the updated *Community Guide* to recommend patient navigators as a standalone intervention or a combined resource with CHWs.

In terms of policy, a number of patient navigation policies have been released over the past 10 years. Regardless of policies related to Medicaid reimbursement, credentialing or other factors, patient navigation has become a standard of care. ACA language highlights patient navigators and CHWs as resources to promote the community health workforce. ACA reauthorized the Patient Navigation Outreach and Chronic Disease Prevention Act of 2005 to allow HRSA to devote more funding and support to its navigation programs. Patient navigation has been acknowledged in the National Prevention Strategy and Institute of Medicine reports.

As of January 1, 2015, the Commission on Cancer will require all institutions to establish a patient navigation process to maintain existing credentials or secure new accreditation. The Centers for Medicare and Medicaid Services (CMS) recently revised an existing rule that provides states with greater flexibility for Medicaid reimbursement of patient navigators and CHWs. However, states that exercise this option must comply with rigorous CMS regulations, such as developing a state plan, clearly identifying and describing all covered services, and creating a training and credentialing program for patient navigators and CHWs. Florida, Massachusetts, Minnesota and Texas already have taken advantage of the revised CMS rule.

In terms of NBCCEDP, case managers/patient navigators are used by 93% of grantees to assist clients through screening and by 97% of grantees to assist clients through diagnostic testing. The high uptake is due to the longstanding coverage of case management/patient navigation costs in the 60% portion of the NBCCEDP 60/40 requirement.

Despite the historical use and wide implementation of patient navigation in NBCCEDP, challenges with this strategy have persisted over time. The existing patient navigation evidence base is limited, particularly with respect to the efficacy of specific models. Standardized process and outcome metrics for patient navigation are lacking. Data systems to capture information related to patient navigation are inadequate. CDC's access to screening data is limited if NBCCEDP funding supports patient navigation, but does not pay for screening. Competencies have not been clearly defined to date for patient navigators. Patient navigation training is not accessible to all 67 BCC Programs.

In terms of ongoing activities, DCPC is conducting a Patient Navigation Measurement Project, patient navigation research and evaluation studies, and a formative study of patient navigation utilization in FQHCs. DCPC is continuing to compile data from annual grantee surveys to monitor the delivery of patient navigation services in NBCCEDP and the Colorectal Cancer Control Program. DCPC has established key internal and external partnerships with other parts of CDC, HHS and the American Cancer Society (ACS) to facilitate a national dialogue and improvements in patient navigation.

Dr. DeGroff concluded her overview by asking BCCEDCAC to address the following questions in providing guidance to CDC on the future direction of NBCCEDP patient navigation activities in a health reform environment.

1. What are appropriate public health models for patient navigation?
2. Can the scope of patient navigation activities be expanded, while including this strategy as a 60% expense in the 60/40 requirement? For example, patient navigators could be trained to make community-clinical linkages.
3. What approaches can be taken to sustain patient navigation activities over time? What costs potentially could be transferred to health systems?
4. Should clinical data be collected on patients who are screened with non-CDC funds, but are navigated by NBCCEDP?
5. Should CDC collect patient-level or aggregate data on the delivery and outcomes of patient navigation services (e.g., rates of screening adherence and timely follow-up)?
6. What are the best approaches for CDC to support training of patient navigators across all 67 BCC Programs?
7. What is the potential impact of credentialing and Medicaid reimbursement of CHWs and patient navigators on NBCCEDP?

BCCEDCAC devoted its entire discussion to addressing the 7 questions posed by Dr. DeGroff regarding the impact of ACA on NBCCEDP's patient navigation activities.

Question 1: Public Health Models for Patient Navigation
• Connecticut is exploring the possibility of demonstrating the value of patient navigators/ CHWs and including these resources in a fee-for-service model as a part of its state Innovation Model Grant. • Nebraska has demonstrated the efficacy of patient navigation across the entire cancer continuum of care: identifying, engaging, recruiting and enrolling women in the BCC Program; making appropriate referrals; and providing case management to women with abnormal screening results. Nebraska's data have shown that patient navigation is essential in meeting the MDE indicator for timely diagnosis and also plays an important role in long-

term survivorship.

Question 2: Expanded Scope of Patient Navigation Activities in the 60/40 Requirement

- CDC should ask all BCC Programs to submit profiles describing the experiences, functions, services and reach of their patient navigators. The compilation and review of individual grantee data would provide CDC with a national picture of the range of services provided by patient navigators. This effort would inform CDC's decision-making process on whether the scope of patient navigation activities can be expanded in NBCCEDP at this time.
- Patient navigation activities should be expanded by training patient navigators to utilize existing public health models or templates to recruit potentially eligible women for NBCCEDP during the initial encounter in the field. Technology has allowed patient navigators and CHWs to successfully implement this approach in other public health programs to immediately schedule appointments and make services more accessible to the target population.
- "Patient navigation" should be more broadly defined as a clinical service in the 60/40 requirement.
- Uniform standards, skill sets and training should be developed for patient navigators and CHWs to perform client intake covered by the 60% portion of the NBCCEDP 60/40 requirement. Client intake is conducted to determine NBCCEDP eligibility and initiate the enrollment process, but wide variations in this process should be eliminated. Based on the individual BCC Program, client intake can be conducted by a centralized location, provider's office or health department.
- Client intake, client counseling and one-to-one recruitment are covered by the 60% portion of the NBCCEDP 60/40 requirement. However, community-based efforts by patient navigators and CHWs to reach these targets are severely underrepresented in program datasets. Risk reduction, awareness and education efforts, referrals and linkages to primary care will increase as CDC shifts NBCCEDP to a population-based cancer screening program. Indicators should be developed to accurately measure funding that is allocated to these community-based activities.
- Line-items for patient navigation in the 60% requirement and data management, entry and analysis in the 40% requirement should be merged to reflect current technology. Most notably, EMR systems could be designed for patient navigators to more easily conduct data management, entry and analysis functions.
- Patient navigators and CHWs should play a prominent role in the 40% portion of the NBCCEDP 60/40 requirement for partnership development. For example, a relationship should be established with Wal-Mart for patient navigators and CHWs to recruit and enroll women in either NBCCEDP or the Marketplace based on their eligibility. The partnership with Wal-Mart would be particularly useful in accessing hard-to-reach, low-income and rural populations.

Question 3: Sustainability of Patient Navigation Activities

- The emerging field of patient navigation has sufficient momentum at this time to establish goals and include this strategy as one component in the standard of care. To advance this effort for payment, ACS should provide expertise to CDC by precisely defining specific types and skill sets of patient navigators.
- CDC should convene professional societies that serve populations with chronic conditions in addition to cancer (e.g., diabetes, heart disease and lung disease) and extensively utilize

patient navigators. Guidance and recommendations by a larger group of patient navigation advocates are likely to increase funding and support, promote new legislation, and ensure long-term sustainability of the intervention.
Questions 4-5: Collection of Patient Navigation Data
• The role of patient navigators in collecting population-based health data should be clearly defined. Metrics for this effort should be developed as well. • CDC should provide leadership in building the patient navigation evidence base. Effective and cost-effective patient navigation strategies that BCC Programs have successfully adopted and implemented should be compiled, rigorously tested and published in the literature as EBIs.
Questions 6-7: Patient Navigation Training, Credentialing & Medicaid Reimbursement
• Credentialing of patient navigators and CHWs will result in several positive outcomes on the one hand (e.g., implementation of a uniform skill set and stronger capacity to achieve quality outcomes). Credentialing will lead to adverse consequences on the other hand (e.g., exclusion of certain populations). Non-certified patient navigators and CHWs provide valuable services and support to a large proportion of NBCCEDP clients. Medicaid will not reimburse patient navigators and CHWs without a clearly defined intervention and a certification process for these resources. CDC, its federal partners and professional societies should provide strong leadership and decision-making to resolve the disconnect between the benefits and adverse consequences of credentialed versus non-credentialed patient navigators and CHWs. • CDC should review existing recommendations by the American Nurses Association and other professional nursing societies as the first step in developing a clear definition of and standards for patient navigators and CHWs.

Dr. Miller asked BCCEDCAC to consider an additional issue while proposing formal guidance to CDC on the future direction of NBCCEDP in a health reform environment. CDC is exploring the option of expanding NBCCEDP eligibility criteria from 250% FPL to 400% FPL to be consistent with the Marketplace. This change would address the population of NBCCEDP women who enrolled in the Marketplace, but subsequently returned to their BCC Programs due to an inability to pay for diagnostic services. Dr. Miller emphasized that CDC would welcome BCCEDCAC's formal guidance on this issue to inform the decision-making process.

Formulation of BCCEDCAC Recommendations to CDC

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Chair

Dr. Mullen summarized several key points and suggestions that BCCEDCAC raised over the course of the meeting. She asked the members to consider these topics and identify those that should be proposed as formal recommendations to CDC.

- BCC Programs could consider leveraging their strong relationships with state immunization programs to advocate for expanded access to HPV vaccination.
- BCC Programs could consider continuing to strengthen their role in community-clinical linkages.
- BCC Programs could consider building relationships with public health genomics programs in state health departments. These programs could play a valuable role in risk assessment, shared decision-making and other services to support BCC Programs.
- PRCs could play a prominent role in strengthening the evidence base and conducting evaluation for BCC Programs that are constrained in these areas.
- CDC could consider collaborating with HRSA and the HHS Office of the Assistant Secretary for Health (including Healthy People 2020 and the National Prevention Strategy) to clarify the transition process and future direction of NBCCEDP even if Congress does not approve new appropriations language to eliminate the 60/40 requirement.
- BCC Programs could consider collaborating with their state chronic disease partners to begin focusing on shared risk factors for disease in addition to the current mandate to provide BCC screening.
- NBCCEDP only screens 10.6% of eligible women reached for breast cancer and 6.5% of eligible women reached for cervical cancer. A decision could be made on whether estimating the denominator of the total NBCCEDP population reached is the best use of limited resources. A focus on high-risk populations could be considered.
- Several issues could be considered in incorporating a population-based approach and system-level changes into NBCCEDP, such as value- versus volume-based screening with incentives.
- Experiences and lessons learned from HIV, prostate cancer and other programs could be applied in updating the *Community Guide* with new sections on risk assessment and shared decision-making for BCC screening and treatment.
- Key findings from CDC's ongoing demonstration projects to strengthen the partnership between public health and Medicaid could be compiled, disseminated and scaled-up nationally as models for other chronic disease programs.
- More emphasis could be placed on addressing the unique needs and challenges of BCC Programs in tribes and territories.
- Collaborations with professional societies could be enhanced to leverage the expertise of these groups in patient navigation.

BCCEDCAC Recommendations to CDC
1. Prioritize two key populations in NBCCEDP: • Uninsured women, particularly those in non-Medicaid expansion states, who are in the coverage gap created by ACA • Immigrant women for cervical cancer screening
2a. Continue to pursue and fund patient navigators and CHWs as a current activity, priority and public health strategy in NBCCEDP to support BCC screening, diagnosis, treatment and follow-up. 2b. Launch a national dialogue with multiple partners to review existing evidence that documents the value of patient navigation. Apply the findings from this initiative to facilitate the development of a national standard for patient navigation.

	• *Action step*: Existing data should be compiled from BCC Programs and analyzed to develop best practices for patient navigators and CHWs.
3.	Establish system-level improvements as an area of focus for NBCCEDP to enhance screening rates, including a reevaluation of the interpretation of the 60/40 requirement.
4.	Develop value-based metrics for NBCCEDP: • Follow-up and completion rates after an abnormal screening result • The proportion of the total target population reached • The proportion of eligible women enrolled in NBCCEDP or the Health Insurance Marketplace • The rate of non-adherence to guidelines, particularly over-utilization of cervical cancer screening
5.	Scale-up the Innovation Projects with FQHCs and Medicaid nationally to assist other public health programs in overcoming barriers to establishing and sustaining these partnerships.
6.	Evaluate the capacity of NBCCEDP to improve health equity and decrease health disparities in BCC mortality.
7.	Maintain the current NBCCEDP eligibility criteria at ≤250% FPL to retain the focus on the hardest-to-reach women.
8.	Develop and disseminate guides on risk assessment and shared decision-making to both providers and patients. Use multiple distribution platforms in this effort.
9.	Explore alternative screening modalities for cervical cancer in NBCCEDP that are aligned with the 2013 World Health Organization guidelines for HPV testing with self-collection methods. Prioritize this initiative in settings without an established or effective PATH Program.
10.	Explore strategies to ensure that underserved, vulnerable populations have access to breast, cervical and colorectal cancer screening.

Chair's Call for a vote	Motion properly made by Dr. Ned Calonge for BCCEDCAC to adopt and submit the formal recommendations to CDC for consideration and action Motion seconded by Dr. Marcus Plescia
Outcome of vote	**Motion unanimously passed by 11 BCCEDCAC voting members**
Next steps	Dr. Mullen will finalize NBCCEDP's formal recommendations for submission in a letter to the HHS Secretary and CDC Director.

Public Comment Session

Ms. Blackmon opened the floor for public comments; no participants responded.

Closing Session

Dr. Mullen thanked the BCCEDCAC members for continuing to contribute their expertise and provide sound guidance to CDC. Ms. Wong and Dr. Berman also thanked BCCEDCAC for providing insightful input on the future direction of NBCCEDP in a health reform environment. They confirmed that CDC would consider and take action on BCCEDCAC's recommendations to the extent possible. CDC's progress in responding to the recommendations would be reported during the next meeting. The participants applauded DCPC staff for planning and organizing an extremely productive meeting and Dr. Mullen for her continued leadership of BCCEDCAC.

With no further discussion or business brought before BCCEDCAC, Ms. Blackmon adjourned the meeting at 11:56 a.m. on November 7, 2014.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

_____
Date

_____
Jewel Mullen, MD, MPH, MPA
Chair, Breast and Cervical Cancer Early Detection and Control Advisory Committee

Attachment 1
Published Meeting Agenda

MEETING OBJECTIVES:
Committee members are charged with advising the Secretary, Department of Health and Human Services (DHHS), and the Director, Centers for Disease Control and Prevention (CDC), regarding the early detection and control of breast and cervical cancer. Committee members will discuss and make recommendations regarding national program goals and objectives; implementation strategies; and program priorities.

Day 1: Thursday, November 6, 2014

9:00 A.M. – 9:10 A.M.	**Opening: Welcome and Roll Call** *Jameka Blackmon, MBA,CMP* Designated Federal Officer, DCPC, CDC
9:10 A.M. – 10:00 A.M.	**Advisory Committee Role and Responsibility** *Demetria Gardner* Committee Management Specialist MASO, CDC *Terry Wheeler* Conflict of Interest Specialist MASO, CDC
10:00 A.M. – 10:30 A.M.	**Introductions of BCCEDCAC Members and Overview of Agenda** *Jewel M. Mullen, MD, MPH, MPA* Commissioner, Connecticut Department of Public Health BCCEDCAC Committee Chair
10:30 A.M. – 10:45 A.M.	**Division of Cancer Prevention and Control Update** *Pamela Protzel Berman, PhD, MPH* Acting Director, DCPC, CDC *Faye Wong, MPH* Chief, Program Services Branch, DCPC, CDC

10:45 A.M. – 11:00 A.M.	**Break**
11:00 A.M. – 12:30 P.M.	**Impact of ACA on the National Breast and Cervical Cancer Early Detection Program** *Jacqueline Miller, MD* Medical Officer, DCPC, CDC **Nebraska Experience** *Melissa Leypoldt, RN* Program Director, Women's & Men's Health Programs Nebraska Health and Human Services **Massachusetts Experience** *Felicia Solomon Tharpe, MPH* Public Health Advisor, DCPC, CDC **Connecticut Experience** *Jewel M. Mullen, MD, MPH, MPA* Commissioner, Connecticut Department of Public Health BCCEDCAC Committee Chair **North Carolina Experience** *Marcus Plescia, MD, MPH* Director, Mecklenburg County Health Department **Group Discussion** *Jewel M. Mullen, MD, MPH, MPA* Commissioner, Connecticut Department of Public Health BCCEDCAC Committee Chair
12:30 P.M. – 1:30 P.M.	**Lunch**
1:30 P.M. – 3:30 P.M.	**Population-based Activities to Increase Appropriate Screening Among Women** **NBCCEDP/Medicaid Demonstration Projects** *Frank Bright, MS* Consultant, National Association of Chronic Disease Directors (NACDD) **NYS Innovation Project with FQHCs** *Teri Larkins, PhD* Public Health Advisor, DCPC, CDC

	MN Innovation Project with Medicaid *Valerie Richmond-Reese, MSW* Public Health Analyst, DCPC, CDC **Group Discussion** *Jewel M. Mullen, MD, MPH, MPA* Commissioner, Connecticut Department of Public Health BCCEDCAC Committee Chair
3:30 P.M. – 3:45 P.M.	**Break**
3:45 P.M. – 4:30 P.M.	**Group Discussion: NBCCEDP Role in Helping Providers Make Appropriate Risk Assessments and Shared Decision Making Tools** *Jewel M. Mullen, MD, MPH, MPA* Commissioner, Connecticut Department of Public Health BCCEDCAC Committee Chair
4:30 P.M. – 4:45 P.M.	**Public Comment** *Jameka Blackmon, MBA,CMP* Designated Federal Officer, DCPC, CDC
4:45 P.M. – 5:00 P.M.	**Wrap-Up/Announcements** *Jewel M. Mullen, MD, MPH, MPA* Commissioner, Connecticut Department of Public Health BCCEDCAC Committee Chair *Jameka Blackmon, MBA,CMP* Designated Federal Officer, DCPC, CDC
6:00 P.M.	**Optional Dinner**

Day 2: Friday, November 7, 2014

9:00 A.M. – 9:15 A.M. **Highlights and Review: Day 1**

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Committee Chair

9:15 A.M. – 10:45 A.M. **Implications for Program Changes**

Jacqueline Miller, MD
Medical Officer, DCPC, CDC

Transitional Program Policies

Analia Stormo
Public Health Consultant, National Association of Chronic Disease Directors (NACDD)

60/40 Update

Mike Mizelle
Associate Director for Policy, DCPC, CDC

Broader Patient Navigation and Education Practices

Amy DeGroff, PhD, MPH
Program Evaluator, DCPC, CDC

Group Discussion

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Committee Chair

10:45 A.M. – 11:00 A.M. **Break**

11:00 A.M. – 11:45 A.M. **Key Recommendations to CDC**

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Committee Chair

11:45 A.M. – 12:00 P.M. **Public Comment**

Jameka Blackmon, MBA,CMP
Designated Federal Officer, DCPC, CDC

12:00 P.M. – 12:30 P.M. **Review of Meeting and Next Steps**

Jewel M. Mullen, MD, MPH, MPA
Commissioner, Connecticut Department of Public Health
BCCEDCAC Committee Chair

Faye Wong, MPH
Chief, Program Services Branch, DCPC, CDC

12:30 P.M. – 1:00 P.M. **Wrap Up/Announcements/Adjourn**

Jameka Blackmon, MBA,CMP
Designated Federal Officer, DCPC, CDC

Attachment 2
Roster of the BCCEDCAC Membership

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Attachment 3
Participants' Directory

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Jewel Mullen, MD, MPH, MPA (Chair)
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Carolyn Muller, MD
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Mecklenburg County (NC) Health Department

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BCCEDCAC Member Absent

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BCCEDCAC *Ex-Officio* Members Present

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(Proxy for M. Carolyn Aoyama, CNM, MPH)
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CDC Representatives

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Terry Wheeler
Faye Wong, MPH

Guest Presenters

Frank Bright, MS
National Association of Chronic Disease Directors

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National Association of Chronic Disease Directors

Attachment 4
Glossary of Acronyms

Acronyms	Description
ACA	Affordable Care Act
ACS	American Cancer Society
BCC	Breast and Cervical Cancer
BCCEDCAC	Breast and Cervical Cancer Early Detection and Control Advisory Committee
CaST	Cancer System and Tracking
CBOs	Community-Based Organizations
CCCs	Cancer Control Coalitions
CCP	Care Coordination Program
CDC	Centers for Disease Control and Prevention
CHCANYS	Community Health Care Association of New York State
CHW	Community Health Worker
CMS	Centers for Medicare and Medicaid Services
COI	Conflict of Interest
DCPC	Division of Cancer Prevention and Control
DFO	Designated Federal Officer
EBIs	Evidence-Based Interventions
EMRs	Electronic Medical Records
FACA	Federal Advisory Committee Act
FACs	Federal Advisory Committees
FDR	Financial Disclosure Report
FOAs	Funding Opportunity Announcements
FPL	Federal Poverty Level
FQHCs	Federally Qualified Health Centers
FY	Fiscal Year
GSA	General Services Administration
HHS	U.S. Department of Health and Human Services
HIEs	Health Insurance Exchanges
HIT	Health Information Technology
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
IRB	Institutional Review Board
MDE	Minimum Data Element

Acronyms	Description
NACDD	National Association of Chronic Disease Directors
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NCI	National Cancer Institute
NYS	New York State
PNRP	Patient Navigation Research Program
PRCs	Prevention Research Centers
PY	Program Year
QI	Quality Improvement
SGEs	Special Government Employees
TA	Technical Assistance
UDS	Uniform Data System
USPSTF	U.S. Preventive Services Task Force
WHC	Women's Health Connection